

Healthcare Failure Mode Effects Analysis

Surgical Site Verification

Healthcare FMEA Process

**Step 1. Select the process you want to examine.
Define the scope**

This HFMEA is focused on Wrong Site Surgery. Two Sentinel Event Alerts disseminated by the Joint Commission coupled with increased reporting of Wrong Site Surgery Incidents spurred this Failure Mode Analysis. The complete process will be reviewed with the intent of identifying a single point failure mode that could circumvent the occurrence of a wrong site surgical sentinel event

HFMEA PROCESS

Step 1: Select Process

- This HFMEA is focused on surgical site verification. This is a prospective failure mode analysis to assess weaknesses in our already established surgical site validation procedure

HFMEA PROCESS

Step 2: Assemble The Team

- Orthopedic Surgeon
- OR Nursing
- APU/PPU Personnel
- In Patient Unit Staff
- Chief of Anesthesia
- Chief Nurse
Anesthetist
- Chief of Surgery
- Surgeons

Step 3A Gather information about how the
process works-describe it graphically

Buck Slip Creation



History & Physical



Permit Creation



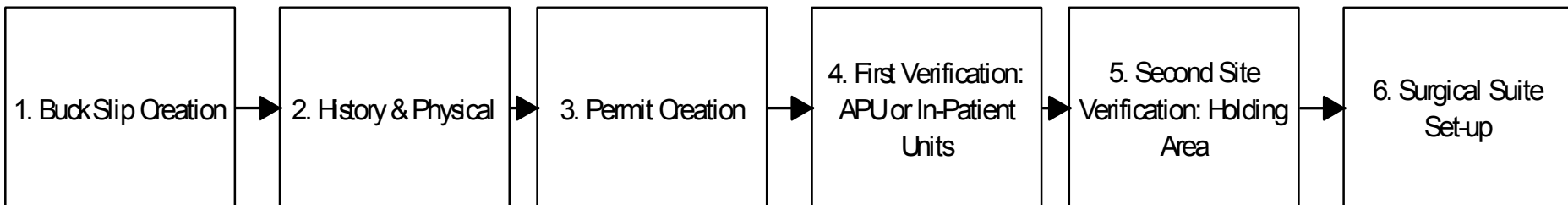
First Verification: APU
or In-Patient Units



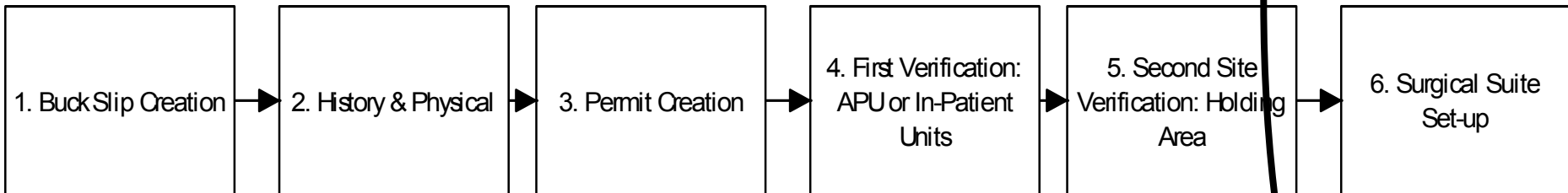
Second Site
Verification: Holding
Area

Surgical Suite Set-up

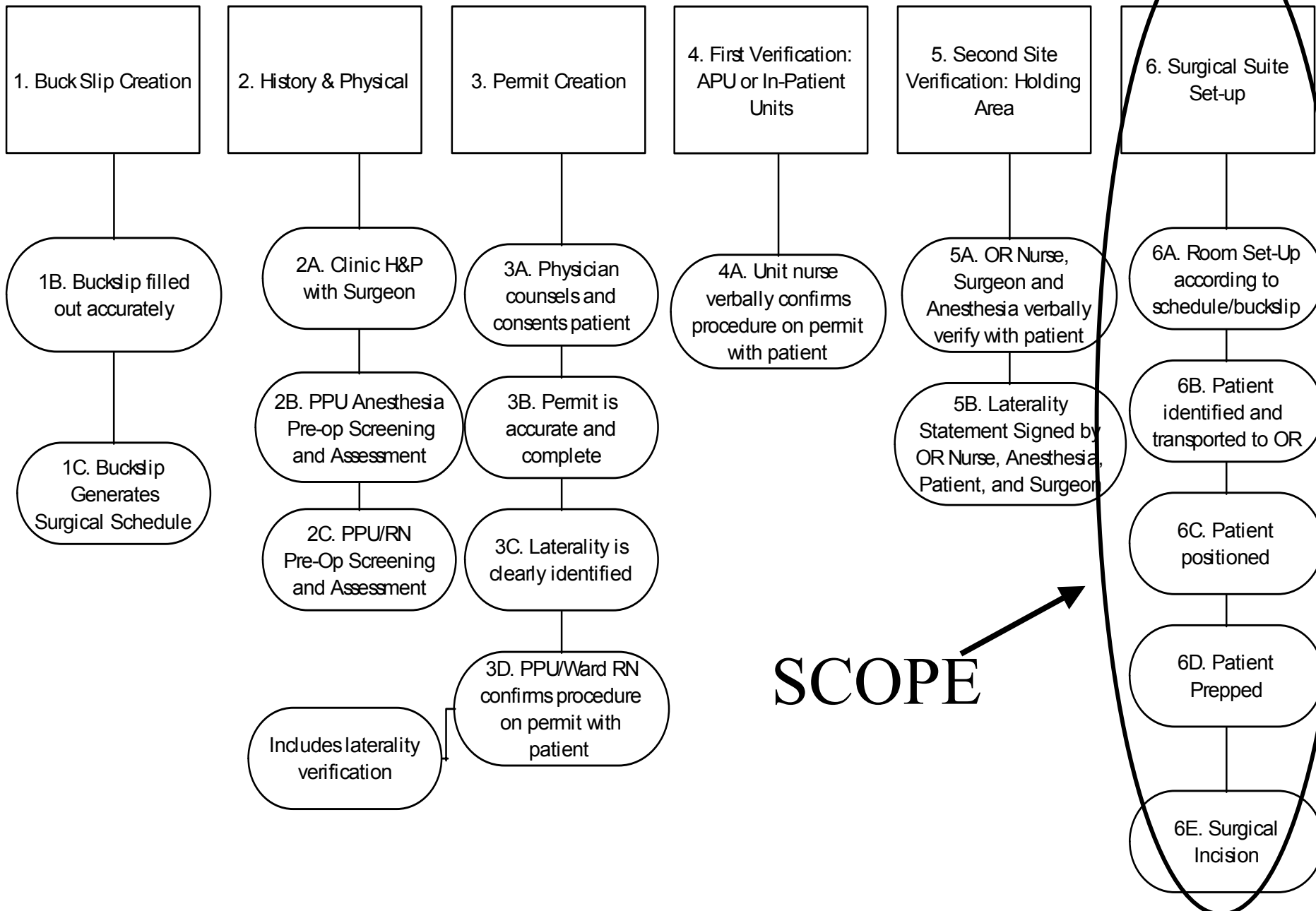
Step 3B. Consecutively number each process step



Step 3C. If proces is complex, choose area to focus

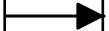


Step 3D. Identify all sub-processes under each block.

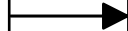


Step 3D Surgical Suite Set-up (Sub-process flow diagram)

6A. Room Set-Up
according to
schedule/buckslip



6B. Patient
Identified and
Transported to OR



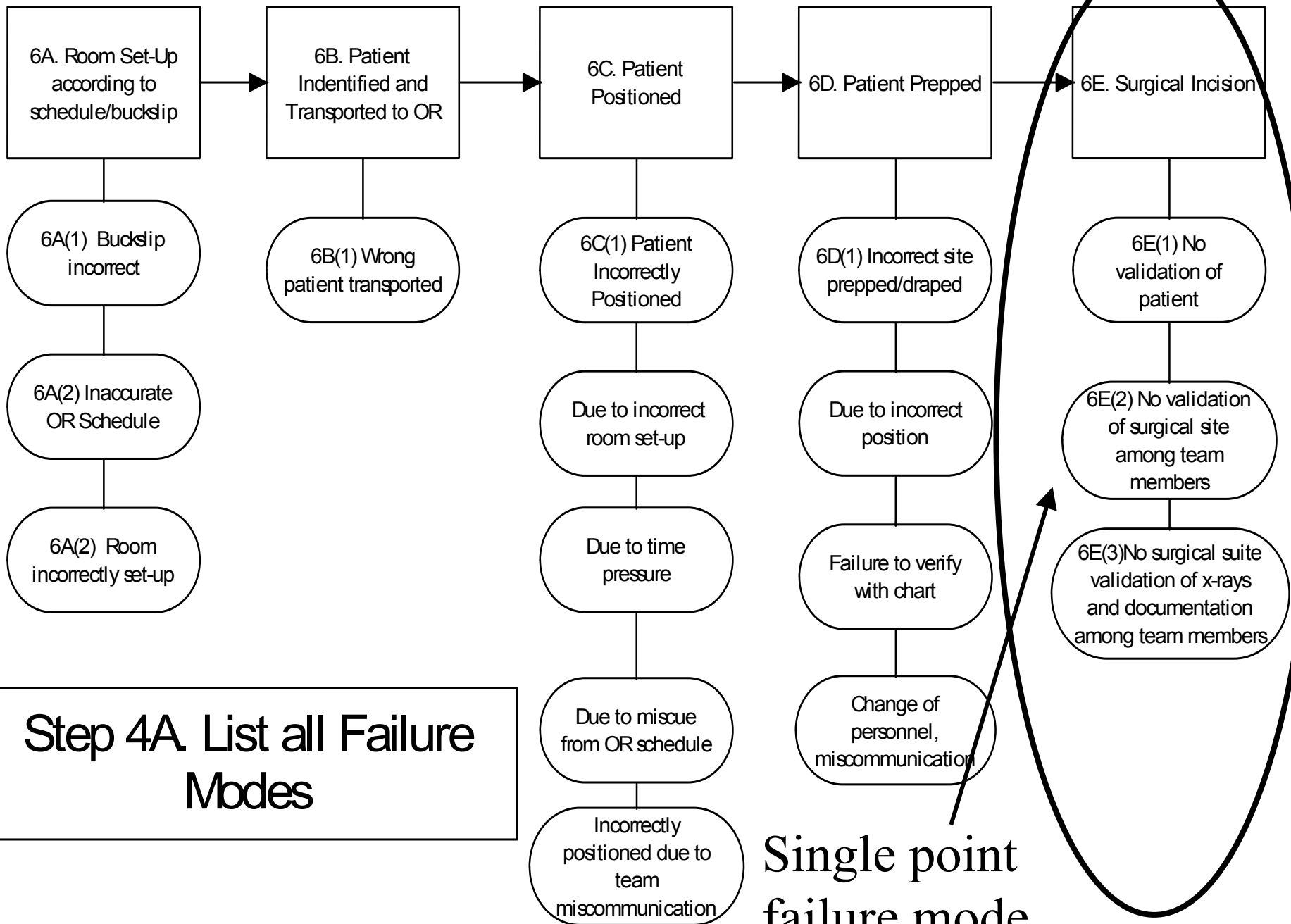
6C. Patient
Positioned



6D. Patient Prepped



6E. Surgical Incision



HFMEA Worksheet, Step 4A

| | | | | |
|--------|----|------------------------|--------------------------------------|--------------------------------------|
| Step 4 | 1 | Process Step | 6E. Surgical Incision | |
| | 2 | Failure Mode | 6E(1). Failure to identify patient | 6E(2) Failure to identify site |
| | 3 | Cause | No joint team identification process | No joint team identification process |
| | 4 | Severity | | |
| | 5 | Probability | | |
| | 6 | Hazard Score | | |
| | 7 | Decision | | |
| Step 5 | 8 | Action | | |
| | 9 | Description of Action | | |
| | 10 | Outcome Measure | | |
| | 11 | Person Responsible | | |
| | 12 | Management Concurrence | | |

HFMEA Worksheet, Step 4A

| | | | | |
|--------|----|------------------------|--|--|
| Step 4 | 1 | Process Step | 6E. Surgical Incision | |
| | 2 | Failure Mode | 6E(3) Failure to validate x-rays, consent, surgical site documentation in OR suite | |
| | 3 | Cause | No joint team identification process | |
| | 4 | Severity | | |
| | 5 | Probability | | |
| | 6 | Hazard Score | | |
| | 7 | Decision | | |
| Step 5 | 8 | Action | | |
| | 9 | Description of Action | | |
| | 10 | Outcome Measure | | |
| | 11 | Person Responsible | | |
| | 12 | Management Concurrence | | |

Step 4: Hazard Analysis

Step 4B. Determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

SEVERITY RATING:

| Catastrophic Event <i>(Traditional FMEA Rating of 10 - Failure could cause death or injury)</i> | Major Event <i>(Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)</i> |
|--|---|
| <p><u>Patient Outcome:</u>Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family</p> <p><u>Visitor Outcome:</u> Death; or hospitalization of 3 or more.</p> <p><u>Staff Outcome:</u> * A death or hospitalization of 3 or more staff</p> <p><u>Equipment or facility:</u> **Damage equal to or more than \$250,000</p> <p><u>Fire:</u> Any fire that grows larger than an incipient</p> | <p><u>Patient Outcome:</u>Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients</p> <p><u>Visitor Outcome:</u> Hospitalization of 1 or 2 visitors</p> <p><u>Staff Outcome:</u> Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses</p> <p><u>Equipment or facility:</u> **Damage equal to or more than \$100,000</p> <p><u>Fire:</u> Not Applicable – See Moderate and Catastrophic</p> |

Step 4: Hazard Analysis

Step 4. Determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

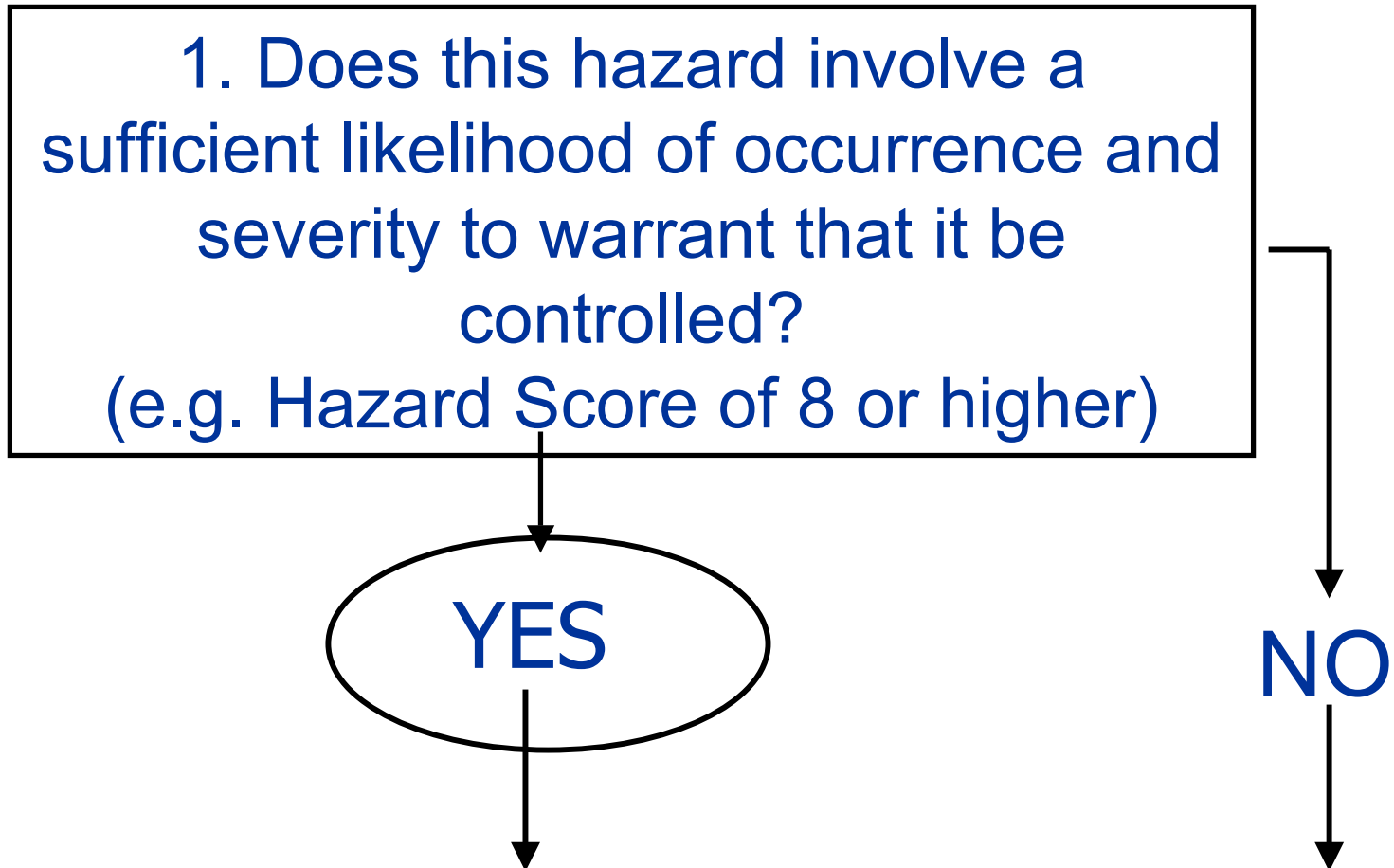
PROBABILITY RATING:

- **Frequent** - Likely to occur immediately or within a short period (may happen several times in one year)
- **Occasional** - Probably will occur (may happen several times in 1 to 2 years)
- **Uncommon** - Possible to occur (may happen sometime in 2 to 5 years)
- **Remote** - Unlikely to occur (may happen sometime in 5 to 30 years)

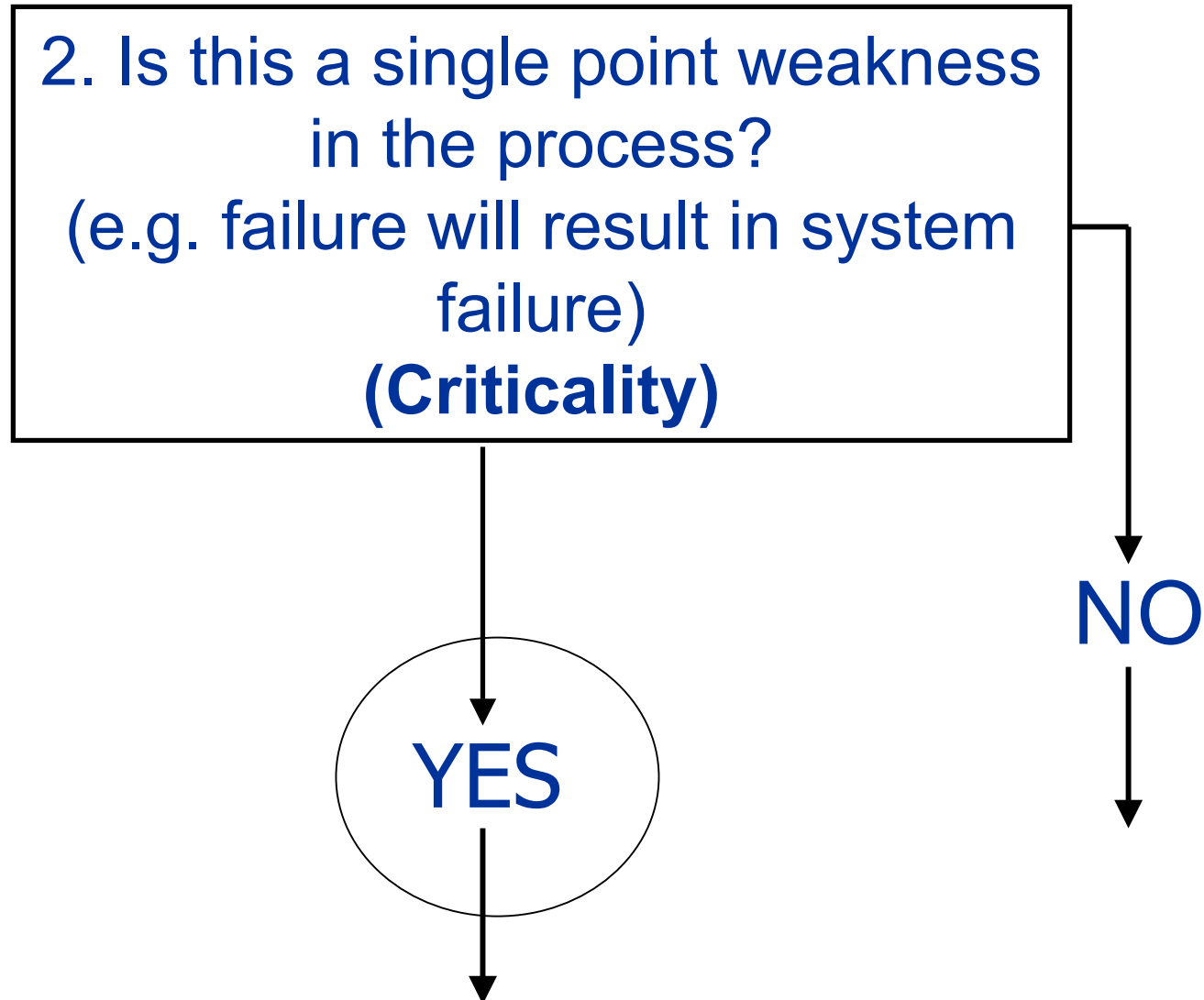
HFMEA Hazard Scoring Matrix

| Probability | Severity | | | | |
|-------------|------------|--------------|-------|----------|-------|
| | | Catastrophic | Major | Moderate | Minor |
| | Frequent | 16 | 12 | 8 | 4 |
| | Occasional | 12 | 9 | 6 | 3 |
| | Uncommon | 8 | 6 | 4 | 2 |
| | Remote | 4 | 3 | 2 | 1 |

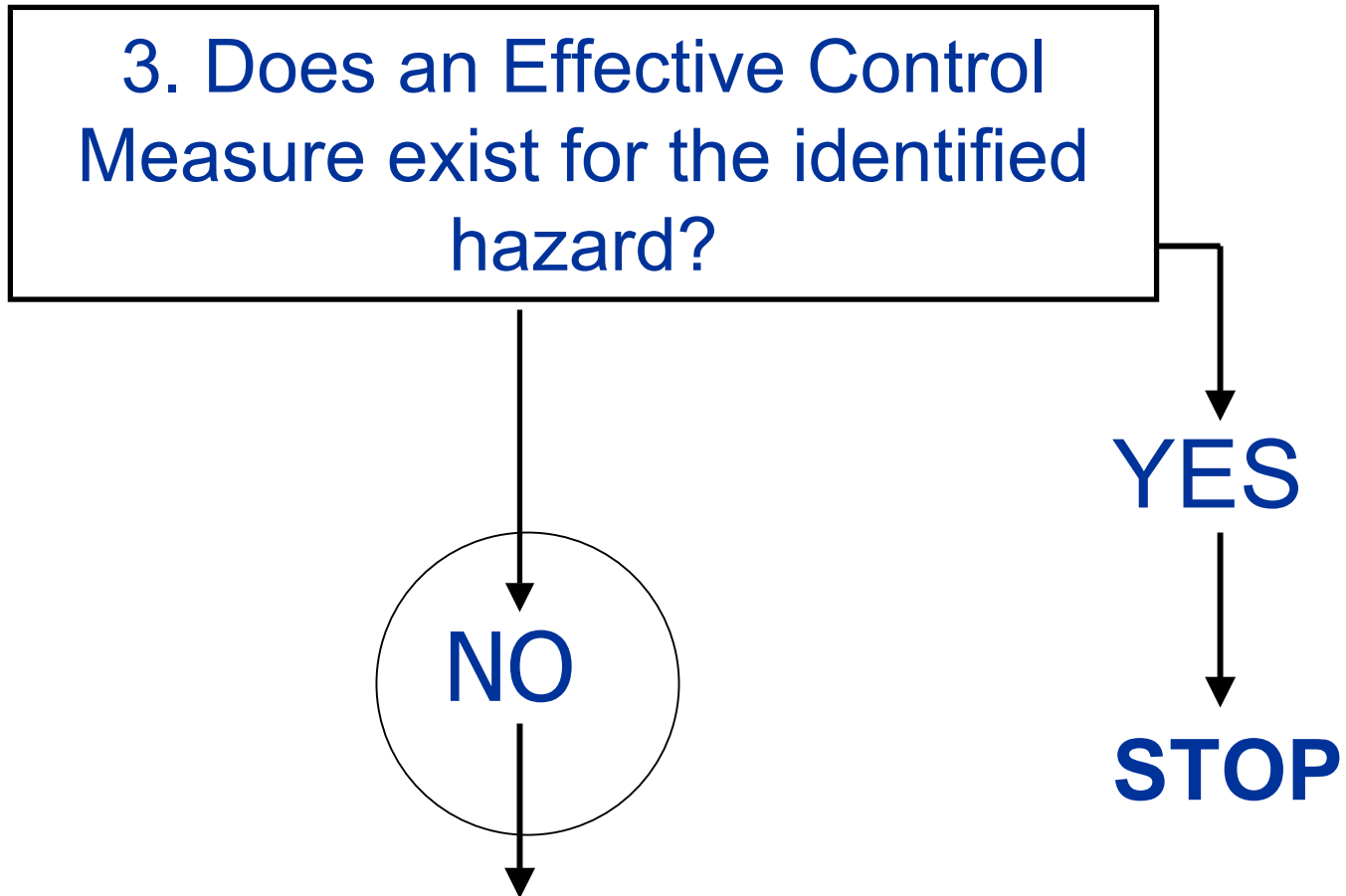
Step 4: HFMEA Decision Tree



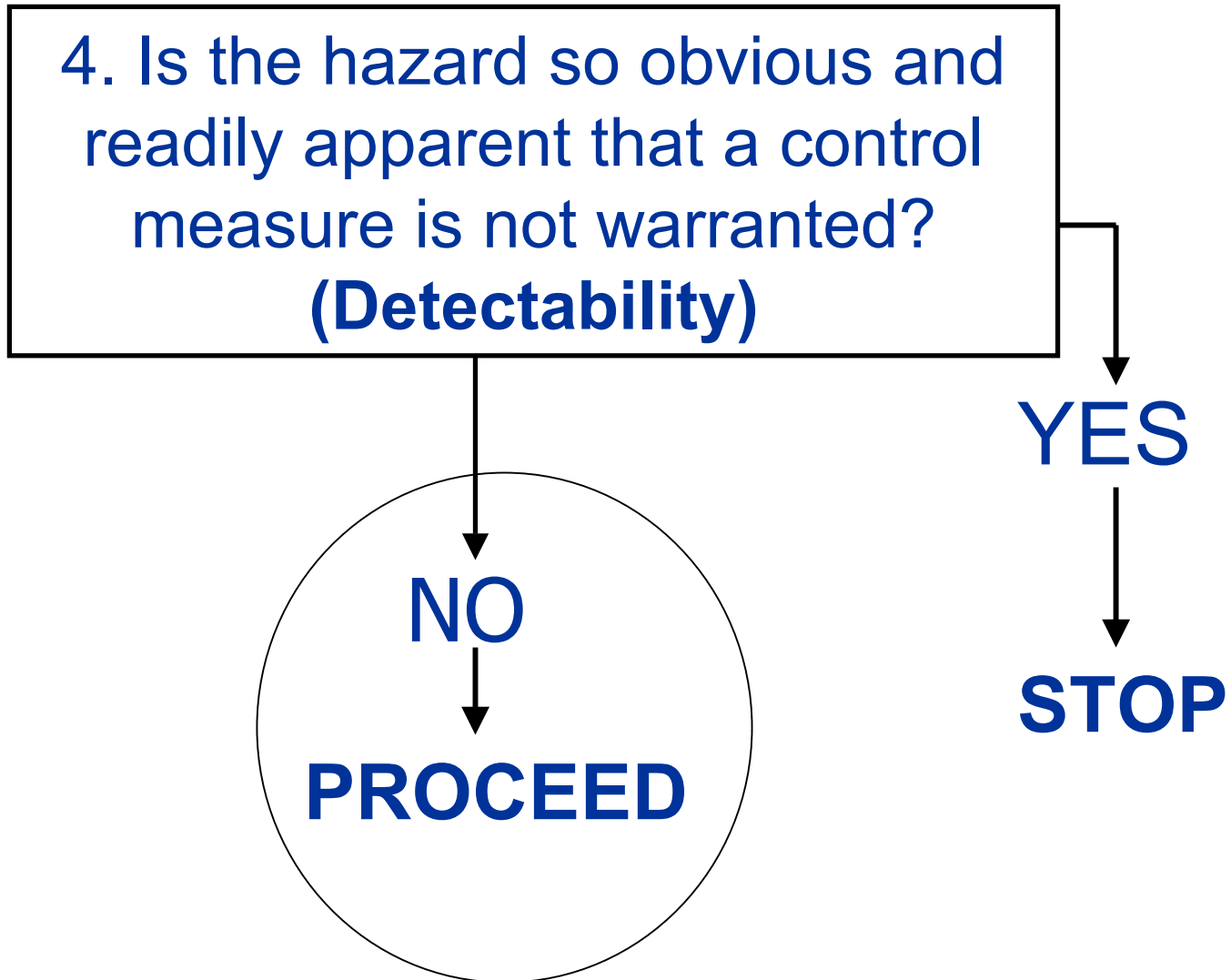
Step 4: HFMEA Decision Tree



Step 4: HFMEA Decision Tree



Step 4: HFMEA Decision Tree



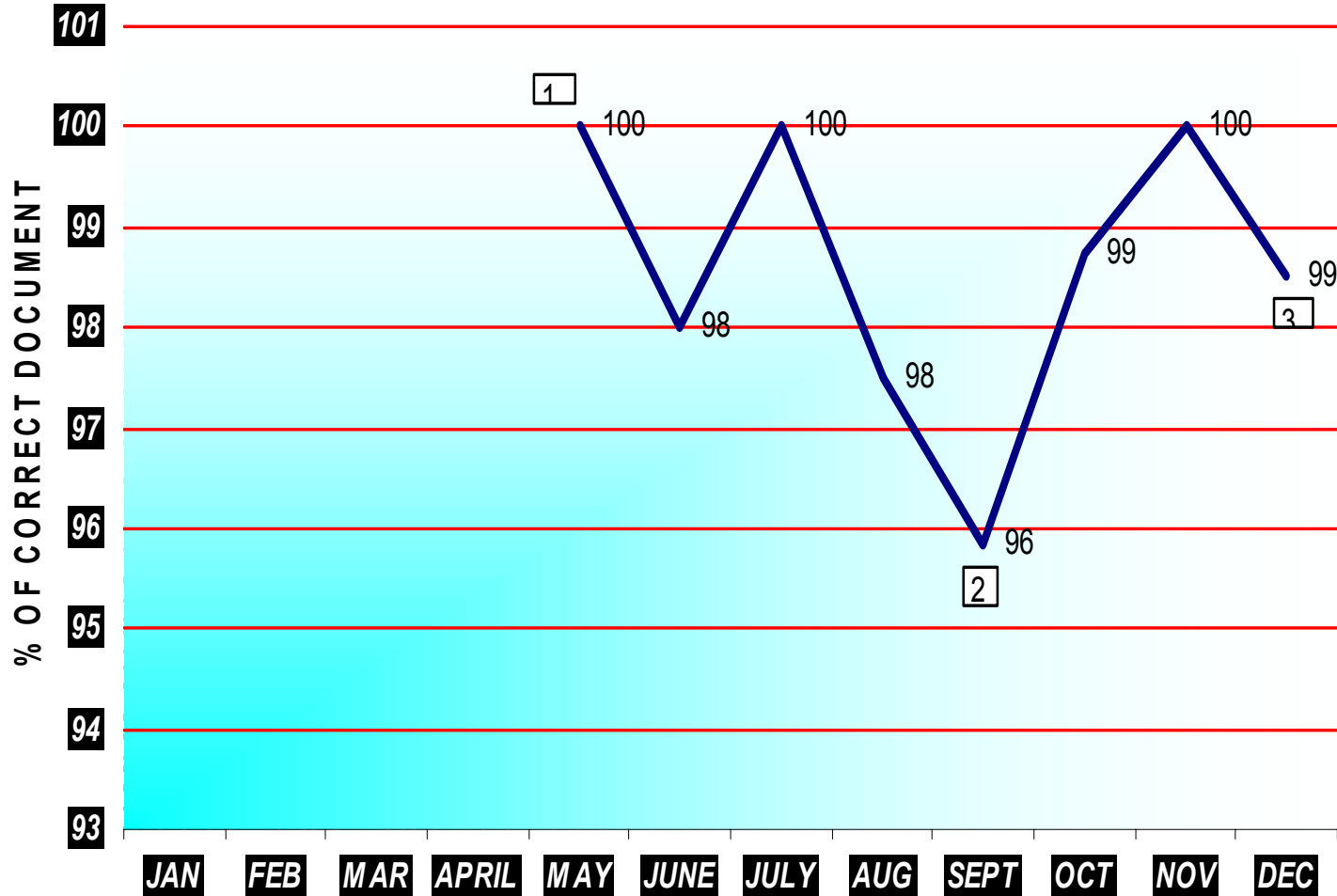
HFMEA Worksheet, Step 4A

| | | | | |
|--------|----|------------------------|--|---|
| Step 4 | 1 | Process Step | 6E. Surgical Incision | |
| | 2 | Failure Mode | 6E(1). Failure to identify patient | 6E(2) Failure to identify site |
| | 3 | Cause | No joint team identification process | No joint team identification process |
| | 4 | Severity | Catastrophic | Catastrophic |
| | 5 | Probability | Uncommon | Uncommon |
| | 6 | Hazard Score | 8 | 8 |
| | 7 | Decision | Proceed | Proceed |
| Step 5 | 8 | Action | Surgical team jointly identifies correct patient | Surgical team jointly identifies and validates surgery site |
| | 9 | Description of Action | Team verbally identifies correct patient | Team verbally confirms correct surgical site |
| | 10 | Outcome Measure | Chart Audits monthly: commence Jan 02 | Chart Audits monthly: commence Jan 02 |
| | 11 | Person Responsible | Surgeon; Anesthesia; OR Nurse; OR Technician | Surgeon; Anesthesia; OR Nurse; OR Technician |
| | 12 | Management Concurrence | Y | Y |

HFMEA Worksheet

| | | | | |
|--------|----|------------------------------|--|--|
| Step 4 | 1 | Process Step | 6E. Surgical Incision | |
| | 2 | Failure Mode | 6E(3) Failure to validate x-rays, consent, surgical site documentation in OR suite | |
| | 3 | Cause | No joint team identification process | |
| | 4 | Severity | Catastrophic | |
| | 5 | Probability | Uncommon | |
| | 6 | Hazard Score | 8 | |
| | 7 | Decision | Proceed | |
| Step 5 | 8 | Action | Team validates surgical consent; xrays, and site verification form | |
| | 9 | Description of Action | Team verbally confirms information using consent; x-rays; site form | |
| | 10 | Outcome Measure | Chart Audits monthly: commence Jan 02 | |
| | 11 | Person Responsible | Surgeon; Anesthesia; OR Nurse; OR Technician | |
| | 12 | Management Concurrence (Y/N) | Y | |

LATERALITY DOCUMENTATION 2001



— LATERALITY 2001

(1) MAY 01:
IMPLEMENTED NEW
DOCUMENTATION AUDITING
TOOL FOR TRIPLE SIGNATURE
COMPLIANCE ON DA 5179

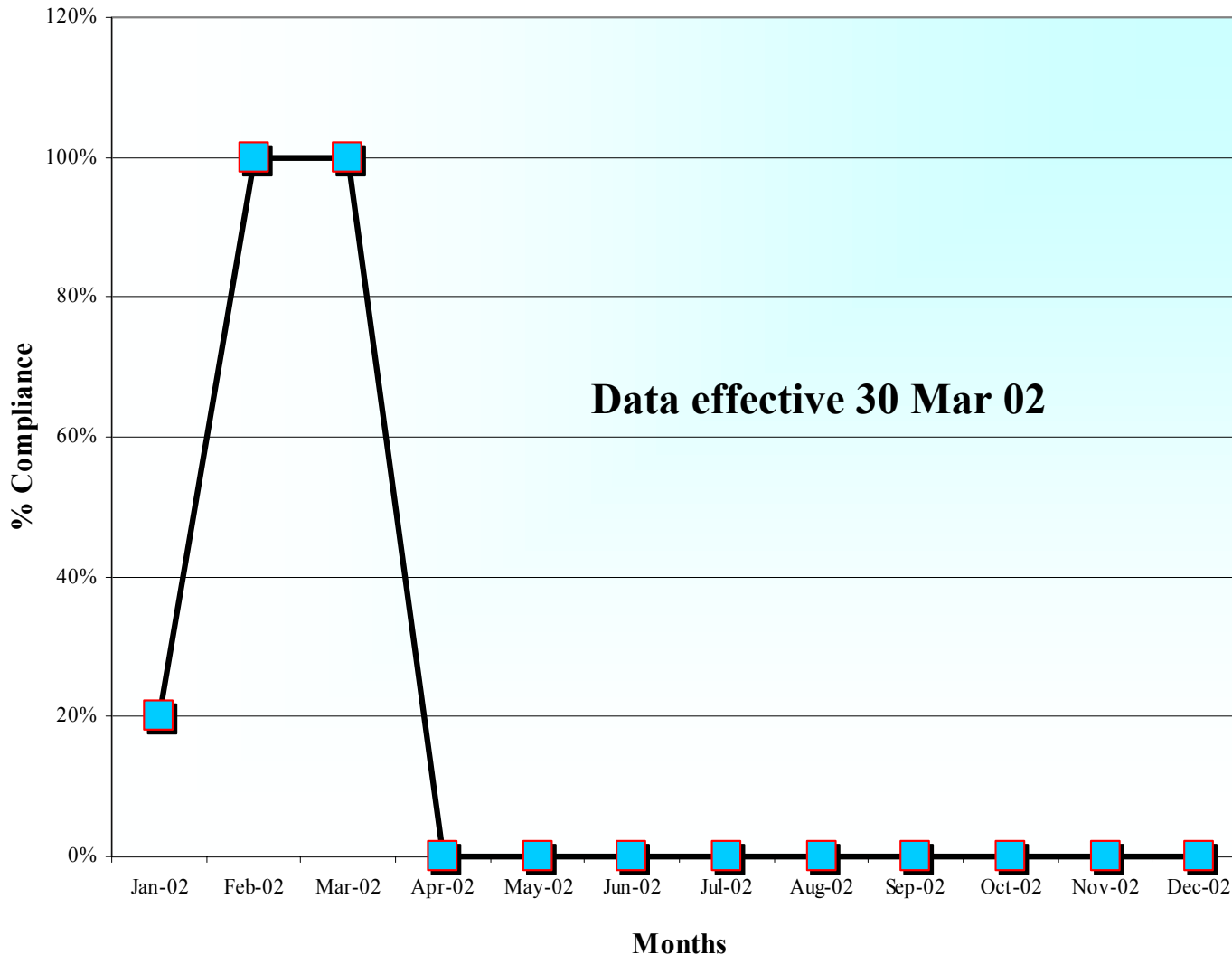
(2) SEPT 01:
SIGNATURE TRENDING BEING
TRACKED FOR SURGEONS,
ANESTHESIA, AND NURSING
ADDITIONAL
ENCOURAGEMENT FOCUSED
ON ANESTHESIA

(3) DEC 01:
EXCEEDED THRESHOLD OF
99% FOR THREE MONTHS;
WILL CONTINUE TO MONITOR

The 3R's in Right-Sided Surgery

Right Patient, Right Procedure, Right Side:

"TIME OUT"



Dec 01: Sentinel Event 24 - recommendation for "Time Out" laterality check before surgical cut. Concept introduced to staff// DOS Chief supporting action - directing compliance by surgeons

Jan 02: SOP finalized inclusive of "Time Out" process. Practice instituted / staff inserviced / DOS Chief - discussed actions required with surgeons at monthly DOS meeting

Feb 02: 2nd inservice given / colorful "reminders" placed in each OR suite / Laterality Compliance Tool created - utilized for each laterality case / Perioperative Documentation to be altered to prompt "Time Out" process through mandatory documentation.

■ % Compliance to "Time Out"
Check: Right Pt, Right Procedure, Right Side